

AMERICAN THORACIC SOCIETY



Quality Control of Pulmonary
Function Testing
Navy Environmental Health Center
Chesapeake, VA



Technician Training

- From Preamble to OSHA Cotton Dust Standard, 1978:
 - “The key to reliable pulmonary function testing is the technician’s way of guiding the employee through a series of respiratory maneuvers;
 - The most important quality of a pulmonary function technician is the motivation to do the very best test on every employee;



Technician Training

- The technician must also be able to judge the degree of effort and cooperation of the subject;
- Test results obtained by a technician who lacks these skills are ***not only useless, but also convey false information which could be harmful to the employee.***



Quality Control

- ACOEM Recommendations
 - Strongly recommends spirometry technicians complete a NIOSH-approved spirometry course.
 - Recommends technicians attend spirometry refresher courses every three (3) years.
 - Recommends providing periodic quality assurance review of spirograms



Quality Control

- Documentation
- Notebook
 - Document problems encountered with system;
 - Corrective action required;
 - System hardware and software upgrades.

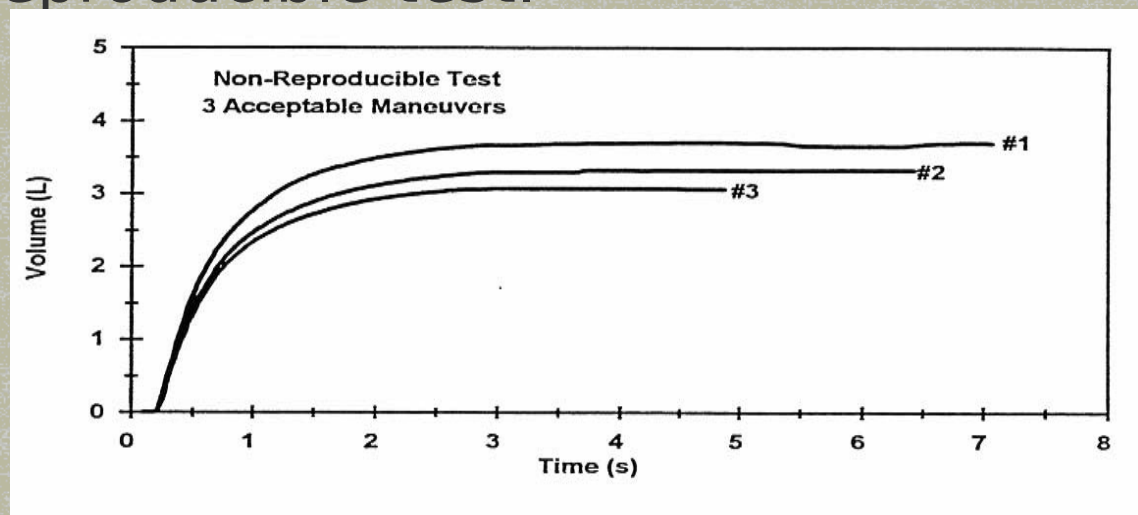


Quality Control

- Technician's role
 - Important element is procedure manual containing:
 - Test performance procedures
 - Calibration procedures
 - Calculations
 - Reference values source; and
 - Action to be taken when “panic” values are observed.

Quality Control

- Provide feedback to technicians
 - Minimum feedback should include
 - Information concerning nature and extent of unacceptable FVC maneuvers and non-reproducible test.





Quality Control

- Provide feedback to technicians
 - Corrective action technician can take to improve quality and number of acceptable maneuvers; and
 - Recognition for superior performance by technician in obtaining good maneuvers from challenging patients.



Quality Control

- Technician needs to be aware of patient-related problems when performing FVC maneuvers
 - Submaximal effort
 - Leaks between lips and mouthpiece
 - Incomplete inspiration or expiration (prior to or during forced maneuvers)
 - Hesitation at start of the expiration

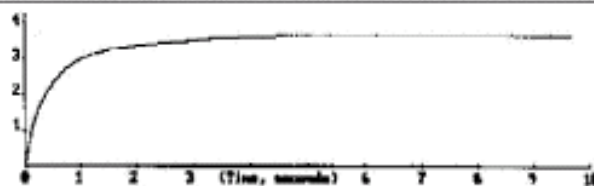
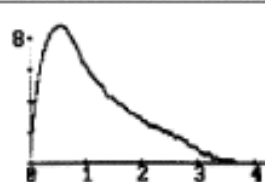


Quality Control

- Cough (particularly within the first second of expiration)
- Glottis closure
- Obstruction of mouthpiece by the tongue
- Vocalization during forced maneuver
- Poor posture

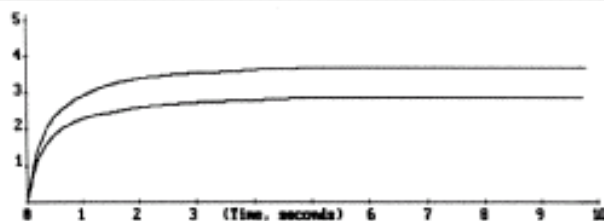
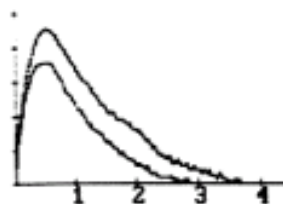


Figure 7-1. GOOD EFFORT



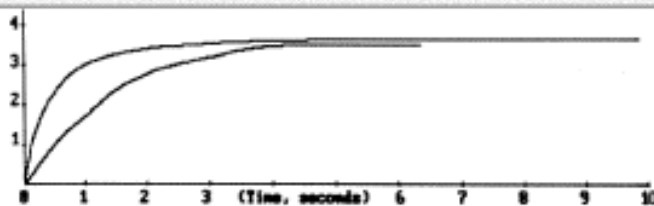
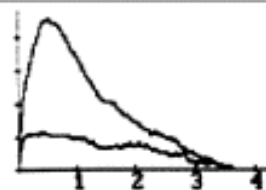
Parameter	Observed	% Pred
FVC (L)	3.93	107
FEV1 (L)	3.23	109
FEV1/FVC, %	82	101

Figure 7-2. SMALL INSPIRATION



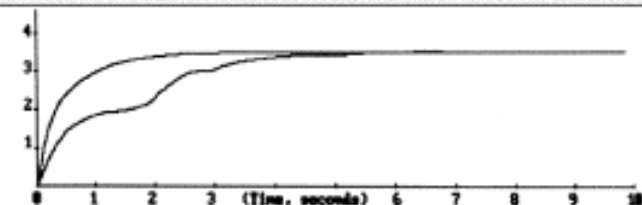
Parameter	Observed	% Pred
FVC (L)	3.11	85
FEV1 (L)	2.48	83
FEV1/FVC, %	80	99

Figure 7-3. WEAK PUSH



Parameter	Observed	% Pred
FVC (L)	3.83	105
FEV1 (L)	1.86	63
FEV1/FVC, %	49	60

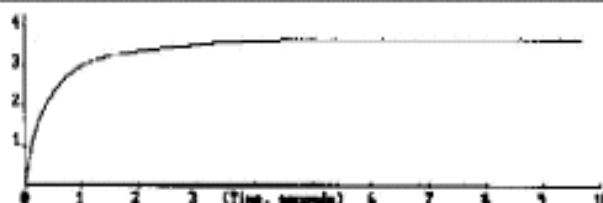
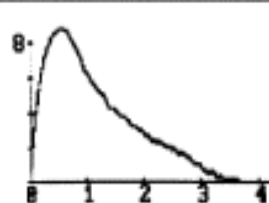
Figure 7-4. TONGUE IN MOUTHPIECE



Parameter	Observed	% Pred
FVC (L)	3.85	105
FEV1 (L)	2.02	68
FEV1/FVC, %	52	64

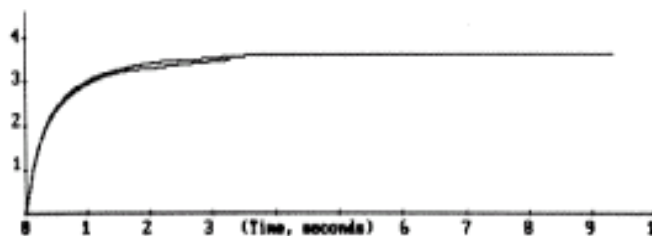
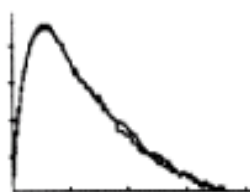


Figure 7-5. GOOD EFFORT



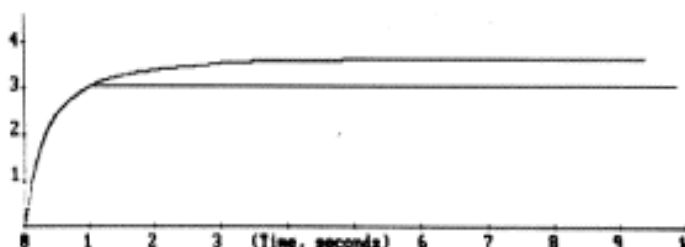
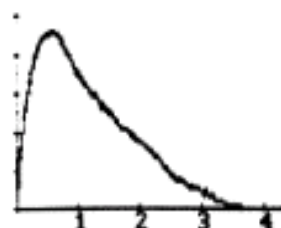
Parameter	Observed	% Pred
FVC (L)	3.93	107
FEV1 (L)	3.23	109
FEV1/FVC, %	82	101

Figure 7-6. EARLY TERMINATION



Parameter	Observed	% Pred
FVC (L)	3.77	103
FEV1 (L)	3.16	106
FEV1/FVC, %	84	104

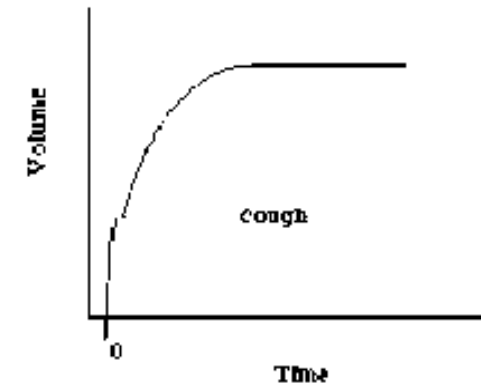
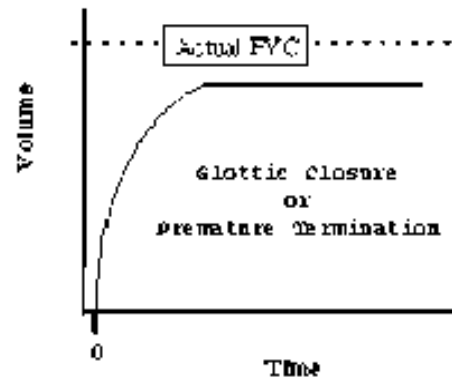
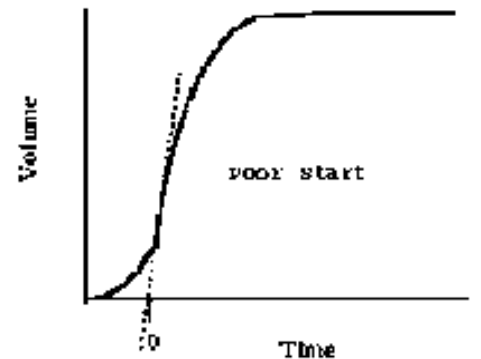
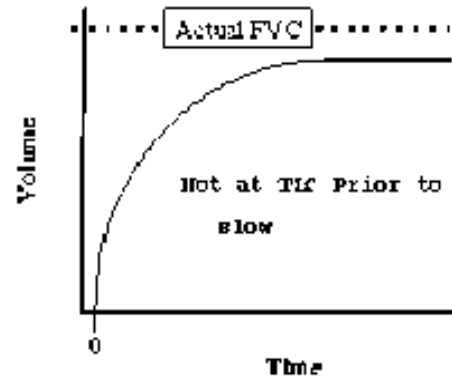
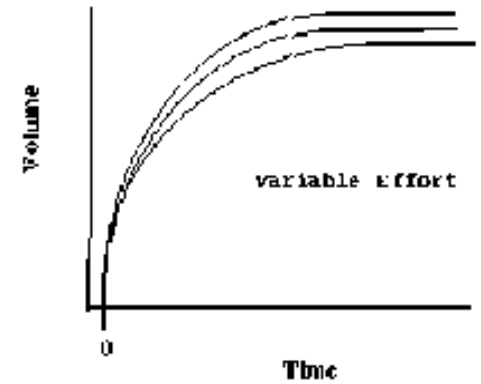
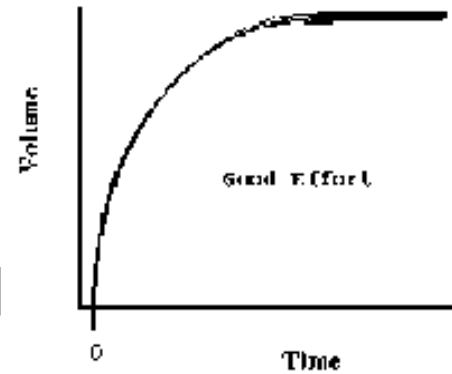
Figure 7-7. GLOTTIS CLOSURE



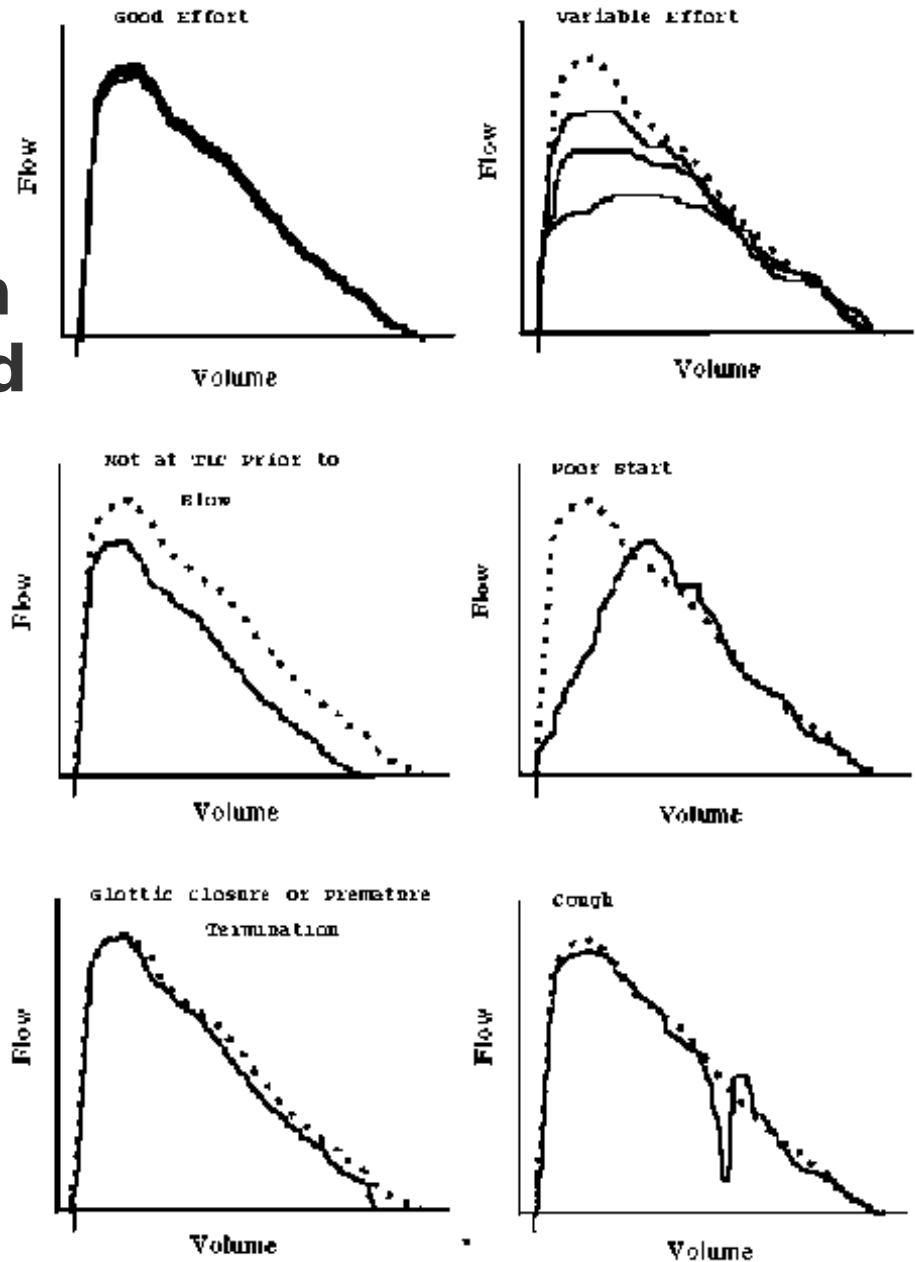
Parameter	Observed	% Pred
FVC (L)	3.31	90
FEV1 (L)	3.27	110
FEV1/FVC, %	99	122



Problematic examples compared with well-performed maneuvers.



**Problematic
examples
compared with
well-performed
maneuvers.**



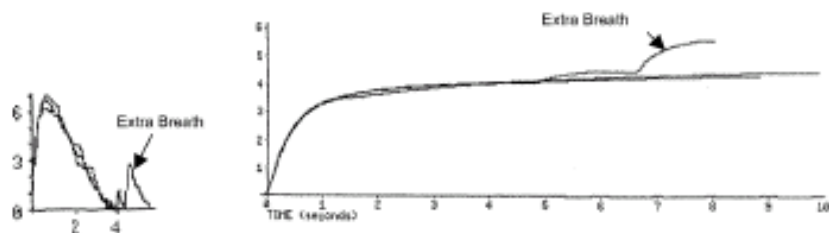


Quality Control

- Errors that inflate test results
 - Poor testing technique
 - Extra breath through nose
 - Slight submaximal expiratory effort
 - Accept/save curve with large hesitation, even when flagged by spirometer
 - Flow-type spirometer malfunctions during subject test
 - Inaccurate zeroing of sensor (performed before each expiration; or
 - Sensor characteristic change between expirations due to warming, deposition of mucous, or condensation of water vapor.

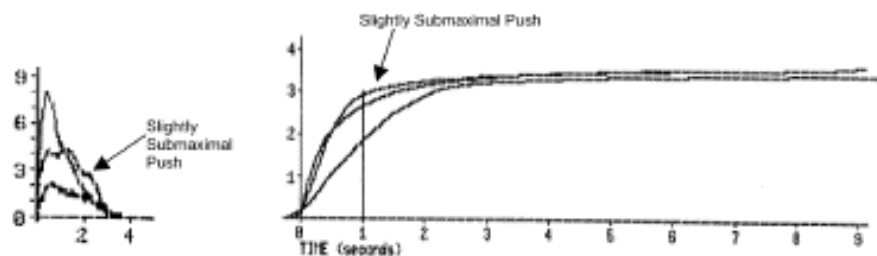


Figure 1: Extra Breath



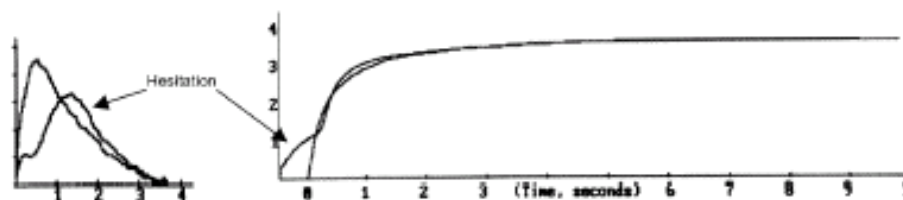
	FVC (L)	% Pred	FEV1/FVC%	% Pred
Good Effort	4.78	96	74	93
Extra Breath	5.96	119	89	76

Figure 2: Slightly Submaximal Expiratory Effort (Negative Effort Dependence of FEV1)



	FEV1	% Pred	FEV1/FVC %	% Pred
Good Effort	2.90	99	74	90
Submax Push	3.13	106	79	96

Figure 3: Excessive Hesitation



	FEV1	% Pred	FEV1/FVC%	% Pred
Good Effort	3.23	100	82	101
Large Hesitation	3.34	112	83	102



Figure 4: Zero Flow Error: Screen Pneumotach

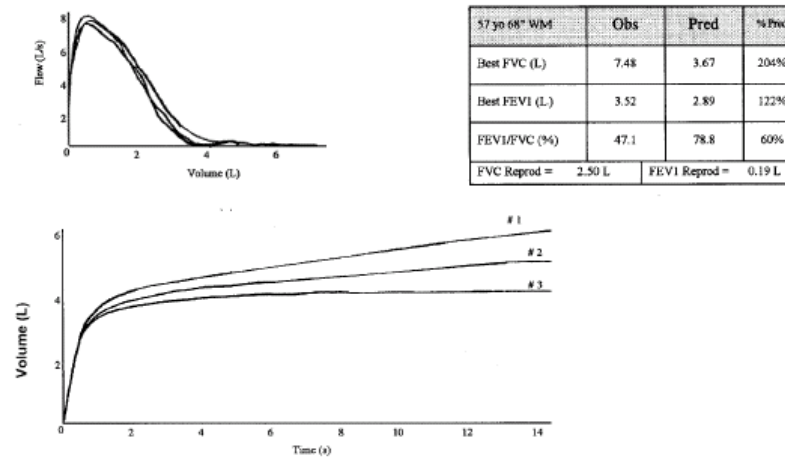
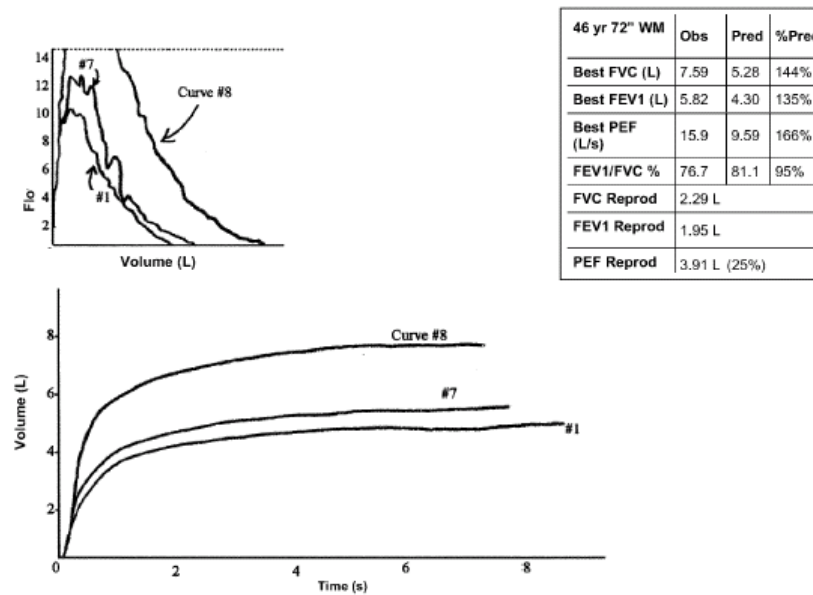


Figure 5: Condensation/ Mucus Deposition: Screen Pneumotach



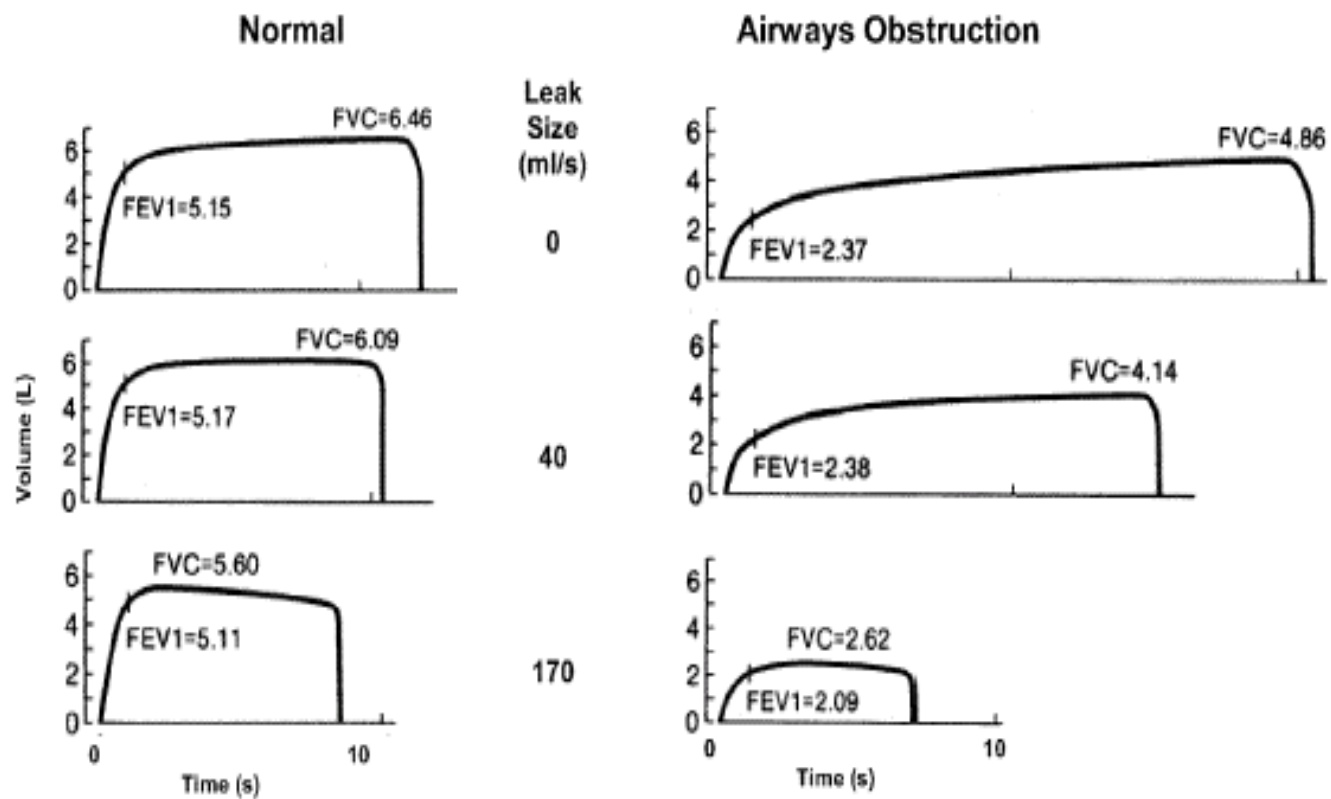


Quality Control

- Error that reduce test results
 - Leaks in volume spirometer or breathing tubes
 - Reduce FVCs significantly but are not visible in spirograms until leak is very large
 - Checking for leaks at least daily in the calibrations check is essential



Figure 6: Effects of Spirometer Leaks on Test Results



Quality Control

■ Hygiene and Infection Control

■ Recommendation:

■ Direct contact

- Potential for transmission of URI, enteric infections, and blood borne infections;
- Most likely surface for contact are mouthpieces and immediate proximal surface of valves or tubing



Quality Control

- Recommendation:
 - Indirect contact
 - Potential for transmission of TB, various viral infections, and possible opportunistic infections and nosocomial pneumonia;
 - Possible contamination of valves and





Quality Control

■ Prevention

- Proper hand washing and/or use of barrier device.
- Use of disposable mouthpieces, nose clips, etc.
- Spirometers using close circuit technique should be flushed at least five time over entire volume range.
- Provide proper attention to environmental engineering control where TB or other diseases are spread by droplet nuclei might be encountered.



Quality Control

■ Prevention

- Take special precaution when testing patients with hemoptysis, open sores on oral mucosa, or bleeding gums.
- Extra precautions with know transmissible infectious diseases.
- Regular use of in-line filters (not mandated).
- Manufacturers encouraged to design instrumentation that can be easily disassembled for disinfection.



Quality Control

- Equipment quality control

- Volume

- Must be checked at least daily with a 3-liter calibrated syringe.

- Syringe accuracy

- Calibration syringe must have an accuracy of at least 15 ml or at least 0.5% of full scale (15 ml for a 3-liter syringe).

- Leak test

- Volumetric spirometry systems must be checked daily.



Quality Control

- Equipment quality control

- Linearity

- Volume spirometers must have their calibration checked over the entire volume range quarterly (in one liter increments).

- Time

- Assessing mechanical recorder time scale accuracy with a stopwatch must be performed at least quarterly.

- Other QA procedures

- Calibration with physical standard (practice of using laboratory personnel as “known subjects”)
 - Adhere to ATS recommendations for computer software for spirometers.



Quality Control

■ Equipment Quality Control

EQUIPMENT QUALITY CONTROL SUMMARY *

Test	Minimum Interval	Action
Volume	Daily	3-L syringe check
Leak	Daily	3 cm H ₂ O constant pressure for 1 min
Linearity	Quarterly	1-L increments with a calibrating syringe measured over entire volume range
	Weekly (flow spirometers)	(flow spirometers simulate several different flow ranges)
Time	Quarterly	Mechanical recorder check with stopwatch
Software	New versions	Log installation date and perform test using "known" subject

* Note: This means on the days you are conducting spirometry tests

EVALUATING CHANGE OVER TIME



Navy Environmental Health
Center
Chesapeake, VA



Key Points

- Why look at change over time?
 - OSHA and industry-mandated programs require health professionals to assess respiratory health using previous and current exam results.
 - Traditional evaluation determines whether test results are in “normal range”, which is based on asymptomatic non-smokers.



Key Points

- Why look at change over time?
 - Many workers have above average lung functions. These can deteriorate dramatically and the loss of function ***will not be detected*** by simply determining whether each year's test results fall within the traditional normal range.
 - Health professional must determine whether monitoring change over time is an effective screening test for outcome disease of interest.



Pitfalls Invalidating Results

- Standardize and document the testing protocol, equipment used and all the changes in protocol or equipment.
- Technician training and periodic QA audits of spirograms.
- Equipment
- Biological variability



Pitfalls

- Standardization/documentation
 - Testing procedures
 - Type of spirometer
 - Spirometer maintenance
 - Quality assurance checks

Pitfalls

- Technician training and periodic QA audits of spirograms





Pitfalls

- Equipment
 - Minimize unnecessary equipment changes.
 - Minimize changes in spirometer configuration.
 - Spirometry accuracy.
 - Save calibration records indefinitely.



Pitfalls

- Biological variability
 - Seasonal variability
 - Postpone test for three (3) weeks if subject has had a severe respiratory infection
 - Postpone test for one hour if subject has had a large meal, smoked a cigarette or used a bronchodilator



Significant Change Over Time

- Quantifying change over time.
 - Deteriorating lung function should be detected early enough to permit the rate of loss to be slowed and remaining function to be preserved.
- What change is significant?
- What if change appears to be significant?



Significant Change Over Time

- What change is significant?
 - If there is a decline in FEV1 and FVC that is greater than 15% in longitudinal screening.
 - The FVC, FEV1, or FEV1/FVC% is less than LLN at any time.
 - There is a 10% decline in the FEV1 between pre- and post-shift screening.



Significant Change Over Time

- What if change appears to be significant?
 - Re-test to confirm low value.
 - Provide medical evaluation, even if test results remain in the traditional normal range.

SPIROMETRY EQUIPMENT



Navy Environmental Health
Center Chesapeake, VA

SPIROMETERS

- Volumetric spirometers
 - Accumulate and directly measure exhaled air volume as a function of time.



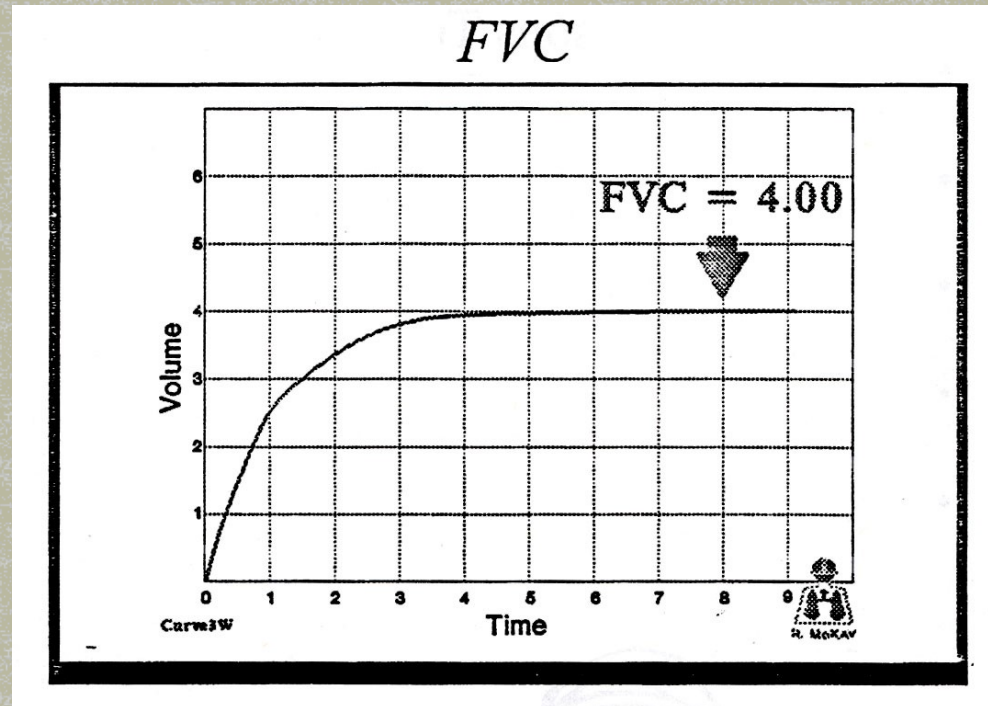


SPIROMETERS

- Volumetric spirometers
 - Water-sealed
 - Dry rolling seal
 - Bellows
- Are precise, simple to operate, and easy to maintain.
- May be slightly unwieldy owing to size and weight.

SPIROMETERS

- Provide direct volume-time tracing.



SPIROMETERS

- Flow-type spirometers
 - Indirectly measure airflow during exhalation; integrate flows to obtain volume



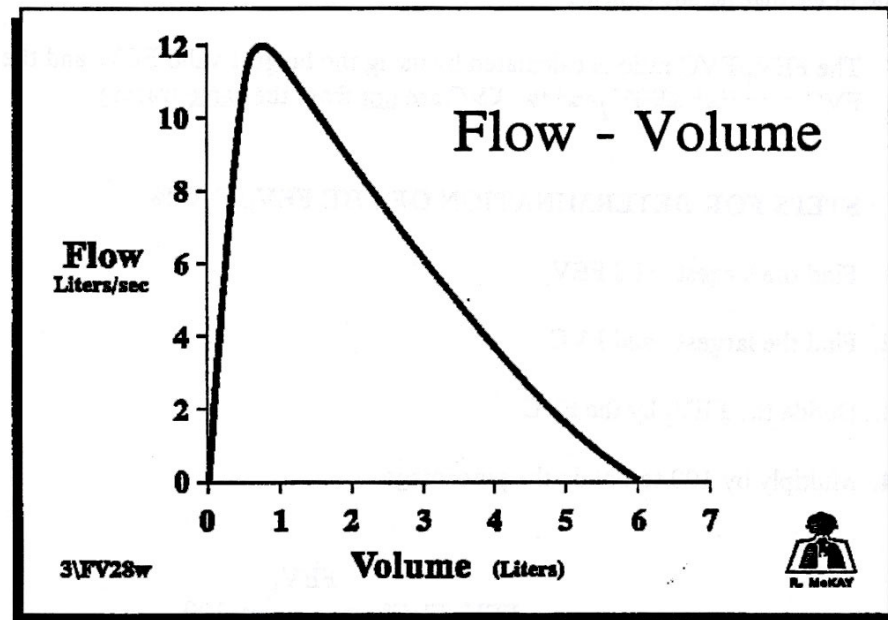


SPIROMETERS

- Flow-type spirometers
 - Pneumotachometer
 - Turbine
 - Hot wire anemometer
- Often more variable (less precise) than volumetric spirometers.
- Lightweight and portable.

SPIROMETERS

- Indirectly measures airflow during exhalation; integrate flows to obtain volume





ATS RECOMMENDATIONS

- ATS Recommendations for volumetric and flow-type spirometers.
 - Minimal performance criteria for range of volumes and flow rate, accuracy, precision, size of graphical display;
 - Validation by laboratory testing with known waveforms to determine whether specific spirometer models meet ATS performance criteria;
 - Frequent quality control (calibration) checks to insure that spirometers remain accurate during use.

MINIMAL RECOMMENDATIONS

MINIMAL RECOMMENDATIONS FOR DIAGNOSTIC SPIROMETRY ¹

Test	Range/Accuracy (BTPS)	Flow Range (L/s)	Time (s)	Resistance and Back Pressure	Test Signal
FVC	0.5 to 8 L $\pm$ 3% of reading or $\pm$ 0.050 L, whichever is greater	zero to 14	15	Less than 1.5 cm H ₂ O/L/s	24 standard waveforms 3-L Cal Syringe
FEV ₁	0.5 to 8 L $\pm$ 3% of reading or $\pm$ 0.050 L, whichever is greater	zero to 14	1	Less than 1.5 cm H ₂ O/L/s	24 standard waveforms
Time zero	The time point from which all FEV ₁ measurements are taken	zero to 14		Back extrapolation	
PEF	Accuracy: $\pm$ 10% of reading or $\pm$ 0.400 L/s, whichever is greater Precision: $\pm$ 5% of reading or $\pm$ 0.200 L/s, whichever is greater	$\pm$ 14		Same as FEV ₁	26 standard waveforms
FEF _{25-75%}	7.0 L/s $\pm$ 5% of reading or $\pm$ 0.200 L/s, whichever is greater	zero to 14	15	Same as FEV ₁	24 standard waveforms

¹ Unless specifically stated, precision requirements are the same as the accuracy requirements.

VALIDATION TESTING LETTER



LDS HOSPITAL
A Service of Intermountain Health Care

Eightth Avenue and C Street
Salt Lake City, Utah 84143
(801) 321-1100

14 August 1996

RE:

The spirometer (serial 1560075, using software version V4M) was tested at the LDS Hospital on 8 August 1996 using a computer-driven spirometry simulator.

The met all the recommendations of the American Thoracic Society (Crapo RO, Chair. Standardization of spirometry: 1994 Update. Official Statement of the American Thoracic Society. Am J Respir Crit Care Med 1995; 152:1107-1136) for accuracy and precision in measuring FVC, FEV₁, FEF_{25-75%} and peak flow.

Sincerely yours,

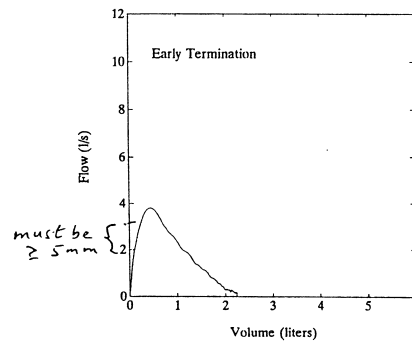
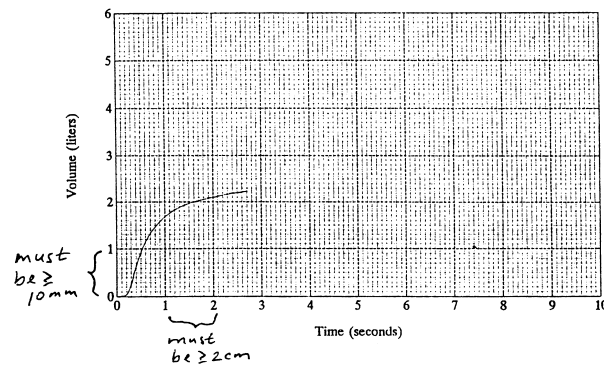
Robert O. Crapo, M.D.
Medical Director, Pulmonary Lab

SCALE FACTORS

TABLE 4

MINIMUM REQUIRED SCALE FACTORS FOR
TIME, VOLUME, AND FLOW GRAPHICS

Parameter	Resolution Required	Scale Factor
Volume	0.025 L	10 mm/L
Flow	0.100 L/s	5 mm/L/s
Time	0.20 s	2 cm/s





Factors to Consider

■ **A spirometer must:**

- Be simple to use;
- Be safe and effective;
- Be capable of simple route calibration;
- Be robust and reliable with low maintenance requirements and have a minimum of 5 to 7 years' design life;
- Provide graphic display of maneuver;
- Be provided with a comprehensive manual describing its operation, routine maintenance and calibrations
- Use relevant normal predicted values; and
- Be reasonably priced

Volume Spirometer

- Vitalograph Gold Standard + (Bellows)
 - Cost: \$4876
 - Vitalograph Inc.
 - (800) 255-6626



Volume Spirometer

- Integrity S700 PFT Analyzer
 - Cost: \$????
 - MEK (Spirotech)
 - (888) 558-5458



Volume Spirometer

- OMI Sensormedic 1022
 - Cost: \$8500
 - Occupational Marketing, Inc.
 - (800)869-6783



Flow-type Spirometers

- Renaissance II
 - Puritan Bennett/Tyco Healthcare
 - Cost: \$2400
 - (800) 635-5267



Flow-type Spirometer

- CDX Spirolab II Spirometer
 - Cost: \$2195
 - CDX Corporation
 - (800) 245-9945



Flow-type Spirometer

- Schiller SP-10
 - Cost: \$3999
 - Welch Allyn Schiller
 - (800) 535-6663



Flow-type Spirometer (Handheld)



Schiller SP-2
\$1320



QRS 1 Spirox card
\$1500



EasyOne
\$1890